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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR        | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|-----------------------------|---------------------|------------------|
| 10/564,451  | 01/12/2006  | Dennis Lee                  | PU60350             | 9864             |
| 20462 7590 11/12/2008<br>SMITHKLINE BEECHAM CORPORATION<br>CORPORATE INTELLECTUAL PROPERTY-US, UW2220<br>P. O. BOX 1539<br>KING OF PRUSSIA, PA 19406-0939 |             |                             |                     |                  |
| EXAMINER<br>YOUNG, SHAWQUITA  |             |                             |                     |                  |
| ART UNIT<br>1626  |             | PAPER NUMBER                |                     |                  |
| NOTIFICATION DATE<br>11/12/2008   |             | DELIVERY MODE<br>ELECTRONIC |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US\_cipkop@gsk.com

### Office Action Summary

**Application No.**

10/564,451

**Applicant(s)**

LEE ET AL.

**Examiner**

SHAWQUA YOUNG

**Art Unit**

1626

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 2, 4 and 16-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 2 and 16-30 is/are allowed.
- 6) ☒ Claim(s) 4, 31 and 32 is/are rejected.
- 7) ☒ Claim(s) 33 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Claims 1, 2, 4 and 16-33 are currently pending in the instant application. Applicants have cancelled claims 5-15 and added new claims 16-33 in an amendment filed on October 27, 2008. The Examiner has **withdrawn the finality** of the previous Office Action and **reopened prosecution** because prior art was found.

#### I. **Response to Arguments/Remarks**

Applicants' amendment, filed on October 27, 2008, has overcome the rejection of claims 1 and 9-15 under 35 USC 112, first paragraph for scope of enablement and the rejection of claims 1 and 9-15 under 35 USC 112, second paragraph as being indefinite. The above rejections have been withdrawn.

#### II. **Rejection(s)**

#### **35 USC § 103 - OBVIOUSNESS REJECTION**

The following is a quotation of 35 U.S.C. § 103(a) that forms the basis for all obviousness rejections set forth in this Office action:

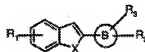
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

*Graham v. John Deere Co.* set forth the factual inquiries necessary to determine

obviousness under 35 U.S.C. §103(a). See *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Specifically, the analysis must employ the following factual inquiries:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

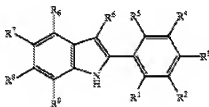
Claims 4, 31 and 32 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Leahy* (US 2002/0037912A1). Applicants claim a pharmaceutical



composition which comprises a compound of formula wherein all variables are as defined in claim 4.

**The Scope and Content of the Prior Art (MPEP §2141.01)**

*Leahy* teaches indole derivatives that are Factor VIIA inhibitors. The invention is represented by the general formula:

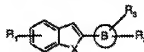


wherein R<sup>1</sup> represents OH; R<sup>2</sup> represents phenyl or nitrophenyl; R<sup>3</sup> represents H; R<sup>4</sup> represents (CH<sub>2</sub>)<sub>0-2</sub>-tetrazolyl or (CH<sub>2</sub>)<sub>0-2</sub>-triazolyl; R<sup>5</sup> represents H; R<sup>6</sup> represents H or CH<sub>2</sub>-phenyl; R<sup>7</sup> represents amino, amidino or guanidine; R<sup>8</sup> represents and R<sup>9</sup> represents H.

**The Difference Between the Prior Art and the Claims (MPEP §2141.02)**

The difference between the prior art of *Leahy* and the instant invention is that there is homologous subject matter. Not all of the substituents are taught, however there is overlap between the substituents disclosed especially in view of the preferred embodiments taught by the prior art. The difference is that the prior art teaches various species where the phenyl ring in the indole group, specifically at the 5-position, is substituted by amidino. However, the prior art also teaches that the amidino group can be replaced amino or guanidino.

**Prima Facie Obviousness-The Rational and Motivation (MPEP §2142-2413)**



Applicants are claiming a compound of the formula

wherein specifically  $R_1$  is absent or represents various substituents including an amino group. The prior art reference of *Leahy* teaches a similar compound wherein the substituent  $R^7$  (equivalent to the  $R_1$  in the instant application) can be various groups including an amino, amidino or guanidino (See page 1, paragraph 0014). The prior art reference also teaches specific compounds such as 2-[2-hydroxy-5-(1H-tetrazol-5-yl)-biphenyl-3-yl]-1H-indole-5-carboxamide, 2-[2-hydroxy-5-(3H-[1,2,3]triazol-4-yl)-biphenyl-3-yl]-1H-indole-5-carboxamidine (See page 1, paragraphs 0018 and 0022). It would be obvious to prepare the above species disclosed in the prior art and replace the amidine group with an amino group because there is a very limited definition for  $R^7$  and have a reasonable expectation of success. Specifically, Applicants compounds read on the

compounds that are disclosed in the prior art. Therefore, it would have been prima facie obvious to one having ordinary skill in the art at the time the invention was made to prepare adjacent homologs based on the teachings of the compounds in the prior art. A strong prima facie obviousness has been established.

### **III. Objections**

#### **Dependent Claim Objections**

Dependent Claim 33 is also objected to as being dependent upon a rejected based claim. To overcome this objection, Applicant should rewrite said claims in an independent form and include the limitations of the base claim and any intervening claim.

#### ***Specification***

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

### **IV. Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawquia Young whose telephone number is 571-272-9043. The examiner can normally be reached on 7:00 AM-3:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shawquia Young/

Examiner, Art Unit 1626

/Kamal A Saeed, Ph.D./

Primary Examiner, Art Unit 1626